

ENZYMATIC THERADY

INCORPORATED

What Better feels like."

INTEGRATIVE THERAPEUTICS INC."

NF Formulas . PhytoPharmica Tyler Encapsulations » Vitaline Formulas

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 - 22 - 4 P: 503.582.8386 * F: 503.582.0467

TOPHARMICA

825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 • F: 888.570.6460 (Enzymatic) P: 920.469.9099 • F: 920.469.4418 (Phyto)

April 27, 2004

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

RE:

Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCTINAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Hot Plants™ for Him	Make sex fun, vibrant, and satisfying for both you and your partner!*	MacaPure (Lepidium meyenii), Yohimbe (Pausinystalia yohimbe) standardized to contain 6% yohimbine, Rhodiola Rosea Extract 3% rosavins, Horny Goat Weed (Epimedium brevicorum) standardized to contain 10% icariin, Panax ginseng root extract standardized to contain a minimum of 7% ginsenosides, Tongkat Ali (Eurycoma longifolia) LJ100

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are sruthful and not misleading.

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

4-30-04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Participal High

Chief Financial Officer

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ENZYMATIC THERAPY & PHYTOPHARMICA*

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April 28, 2004

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHIGH THE CLAIM REFERS
Hot Plants™ for Him	Hot Plants™ formulas successfully enhance and work with your body's innate desire for healthy sex.*	MacaPure (Lepidium meyenii), Yohimbe (Pausinystalia yohimbe) standardized to contain 6% yohimbine, Rhodiola Rosea Extract 3% rosavins, Horny Goat Weed (Epimedium brevicorum) standardized to contain 10% icariin, Panax ginseng root extract standardized to contain a minimum of 7% ginsenosides, Tongkat Ali (Eurycoma longifolia) LJ100

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

 $\mathbf{R}_{\mathbf{V}}$

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/28/04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely

Chief Financial Officer



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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Hot Plants™ for Him	Reclaim your sexuality and your libido with Hot Plants™.*	MacaPure (Lepidium meyenii), Yohimbe (Pausinystalia yohimbe) standardized to contain 6% yohimbine, Rhodiola Rosea Extract 3% rosavins, Horny Goat Weed (Epimedium brevicorum) standardized to contain 10% icariin, Panax ginseng root extract standardized to contain a minimum of 7% ginsenosides, Tongkat Ali (Eurycoma longifolia) LJ100

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are puthful and not misleading.

By: The little

Robert C. Doster
Title: Senior Vice President of Scientific Affairs

Date: 4-30-04

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Michael P. Devereux

Chief Financial Officer